

### **III. REMARKS**

#### **A. Status**

Claims 1-34 are pending and stand rejected.

#### **B. Amendments**

The Abstract has been amended per the Patent Examiner's suggestion on page 2 of the Office Action.

No new matter has been added.

#### **C. Rejections Under 35 U.S.C. §103(a)**

All claims stand rejected under 35 U.S.C. §103(a). Under the guidelines placed into effect on October 10, 2007,<sup>1</sup> when considering obviousness of a combination of known elements, the operative question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." Patent Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness. Office personnel must also provide an explanation to support an obviousness rejection under 35 U.S.C. 103. In short, the focus when making a determination of obviousness is to be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge.

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<sup>1</sup> <http://www.uspto.gov/web/offices/com/sol/og/2007/week45/patguide.htm>

The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 2007 U.S. LEXIS 4745 (April 30, 2007), noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn* stated that “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” Although the Supreme Court in *KSR* cautioned against an overly rigid application of the “teaching-motivation-suggestion” test (“TSM”), it also recognized that TSM was one of a number of valid rationales that could be used to determine obviousness. The others include:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) “Obvious to try” - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art;

- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

**1. Rejection Of Claims 1-14, 17-28, and 31-34**

Claims 1-14, 17-28, and 31-34 stand rejected under 35 U.S.C. §103(a) over Hu (US Patent No. 6,233,304) in view of Kaufman et al. (US Patent Appl. 2003/0095693). Applicants respectfully traverse.

The Patent Examiner admits that Hu's method is not expressly correlated to disease risk assessment and relies on Kaufmann to supply using Hu's method with calcium scoring to assess disease.

Hu does not teach defining a density distribution of calcification within the located area and defining an anatomical distribution of the spots. Instead, Hu teaches away from this by stating "After determining the calcium score for each region of interest, the total calcium score is then determined. **More specifically, a total calcium score is determined for all regions of interest by summing, or adding together, the calcium score from each region of interest.** (emphasis added)" Hu further teaches that where the projection data does not represent evenly and/or contiguous spaced slices, a weighted total calcium score is determined. Generating a total calcium score by summation is different than analyzing the data to determine a distribution of calcification in the patient, e.g. calculating a calcium score by using a density distribution viewed in light of an anatomical distribution of the spots. For example, in various embodiments, the current application teaches that its scoring module 42 or other software perform statistical analyses such as determination of a mean, a median, a mode, a standard deviation, a range, a coefficient of variation, skew, kurtosis, or the like, or a combination thereof. Hu's teachings do not render use of these other mathematical methods obvious.

Moreover, the current application further teaches that in a preferred embodiment, analyzing comprises determining proximal and distal artery calcification, determining the distribution of calcification in multiple coronary branches of the scanned region, determining concentric and eccentric calcification, determining changes in calcification density, determining the size of plaque in calcified areas, determining the shape of plaque in calcified areas, determining the density of plaque in multiple calcified areas, or the like, or a combination thereof. Nothing in Hu renders these obvious, as Hu only teaches determining a total calcium score for all regions of interest by merely summing, or adding together, the calcium score from each region of interest.

**2. Rejection Of Claims 15 and 29**

Claims 15 and 29 are rejected under 35 U.S.C. §103(a) over Hu (US Patent No. 6,233,304) in view of Kaufman *et al.* (US Patent Appl. 2003/0095693) and O'Brien (US Patent Appl. 2004/0057955). As Hu, alone or in view of Kaufman, does not render claims 14 or 28 obvious, the addition of O'Brien does not render Claims 15 or 29, which depend from 14 and 28 respectively, obvious.

**3. Rejection Of Claims 16 and 30**

Claims 16 and 30 are rejected under 35 U.S.C. §103(a) over Hu (US Patent No. 6,233,304) in view of Kaufman *et al.* (US Patent Appl. 2003/0095693) and O'Brien (US Patent Appl. 2004/0057955) in further view of Rather *et al.* (U.S Patent 6,385,474).

As Hu, alone or in view of Kaufman or O'Brien, does not render claims 15 or 29 obvious, the addition of Rather does not render Claims 16 or 30, which depend from 15 and 29 respectively, obvious.

#### **IV. CONCLUSION**

Having been traversed, early acceptance of claims 1-34 is respectfully requested.

Respectfully submitted,

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